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Dealers Workshop DRAFT March 18 & 20, 2003

CHAPTER 20

DEPURATION

- Bullets are **notes** indicated in **blue** for clarification.
- The section number for an existing regulation is noted in brackets [20.01].
- New text or changes proposed in accordance with the **NSSP** compared to the existing regulations are indicated in **red italics**.
- New text or changes proposed by the **Department** in addition to the NSSP are indicated in **bold plum and underlined**.
- The electronic copy is available at www.maine.gov/dmr/

Chapter 20 – Depuration

- **Chapter 20 has been updated for compliance with the NSSP and HACCP rules per federal regulations.**
- **Several sections in Chapter 20 are duplicates of sections that have been consolidated in Chapters 15, 16 or 18. For example, Chapter 16 contains existing section 20.09 Physical Plant, section 20.10 Water Quality rules on process water, plus equipment handling, cleaning, plumbing, sewage and labeling, etc.**

20.01 [15.02, 20.29] Compliance

- A. A violation of this regulation shall be punishable as a Class D crime, as provided by 12 M.R.S.A. §6204, or by license enforcement actions in **District Court**, and may result in the imposition of fines by the District Court for regulation violations.
- B. Each depuration processor shall comply with the requirements specified in Chapter 15, Chapter 16, and Chapter 18 that are appropriate to the plant and the shellfish being processed.**

20.02 [20.01, 20.24] Depuration

- A. The holder of a depuration certificate issued pursuant to 12 M.R.S.A. §6856 may cleanse shellfish harvested from restricted or conditionally restricted areas, using a physical plant and processing methods which are approved by the Commissioner and which comply with the requirements set forth in this chapter.
- B. The holder of a depuration certificate may purchase, receive or harvest shellstock from areas classified as approved, conditionally approved, restricted or conditionally restricted and submits such shellstock to an approved depuration process. The depuration processor may pack, sell, ship or transport the depurated shellstock. A depuration processor shall have a facility, including a means of refrigerated storage of shellfish, i.e. a walk – in cooler.

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20.03 [20.24] Receiving Critical Control Point - Critical Limits.

The depuration processor shall receive and depurate only shellstock, which is:

A. Obtained from a licensed harvester who has:

- 1. Harvested the shellstock from an approved or conditionally approved area in the open status as indicated by the tag; and**
- 2. Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or**

B. Originates from a certified dealer who has identified the shellstock with a tag on each container; or

C. Obtained from an authorized representative in accordance with Chapter 20.07 who has:

- 1. Harvested or supervised the harvest of shellstock from a restricted or conditionally restricted area in the open status; and**
- 2. Identified the shellstock by transaction records, which include the harvest area, the authorized representative's name, the licensed harvester name(s), harvester license number(s), the harvest date, and the amount of shellstock shipped in each lot.**

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20.04 [20.16, 20.20] Processing Critical Control Point - Critical Limits.

The depuration processor shall:

- A. Depurate all lots for a minimum of 44 hours; and**
- B. Monitor the water treatment system that it is operating at design specifications; and**
- C. Monitor that the critical limits established during verification of the specific depuration process are being met.**

20.05 Shellstock Storage Critical Control Point - Critical Limits

The depuration processor shall ensure that:

- A. If onshore wet storage is practiced, water quality meets the requirements outlined in Chapter 15.34 and/or 15.35; and**
- B. Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:**
 - 1. Iced; and/or**
 - 2. Placed in a storage area or conveyance maintained at 45 °F (7.2 °C) or less; and**
 - 3. Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration for more than 2 hours at points of transfer such as loading docks.**
 - (a) Methods other than ice or mechanical refrigeration must be approved by the Department prior to use.**

20.06 *Depuration Process Water*

A. A prohibited growing area shall not be used for source water.

B. The depuration processor shall:

- 1. Continuously treat process water with a disinfection system approved by the Department that does not leave any unacceptable residue in the shellstock; and***
- 2. Verify that the disinfection system produces process seawater with no detectable coliform organisms as measured using an NSSP approved method in the tank influent according to the following sampling protocols:***
 - (a) If the source water is an approved growing are, approved well, or other approved source, then the tank influent produced by each disinfection unit is evaluated once per process batch;***
 - (b) If the source water is a restricted growing area, then:***
 - (i) A study meeting the requirements of Chapter 15.33(K). is required; and***
 - (ii) The tank influent produced by each disinfection unit is verified daily.***

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20.07 [20.24] Harvest of Shellfish for Depuration

- A. Each depuration plant certificate holder shall apply to the Department on an annual basis the names of individuals who are to serve as authorized representatives for the depuration plant in depuration harvesting operations. The Commissioner may refuse to approve the proposed authorized representative(s) where that person(s) has a history of marine resource violations and/or convictions.
- B. The authorized representative shall oversee the members of the depuration harvesting crew and keep accurate records as required in section C below.
- C. The authorized representative shall maintain a current list of all depuration harvest crewmembers and their current, valid shellfish harvester's license number during each day's operation. These lists shall be available for inspection by department personnel at all times.
- D. The authorized representative shall maintain daily records of the quantity of shellfish harvested by each member of the harvest crew, and the area where the shellfish were harvested. These records shall be available for inspection by department personnel at all times.
- E. The depuration plant authorized representative shall call the appropriate Maine State Police communications center to notify the local marine patrol officer of the area of harvest 24 hours prior to actual harvesting.
- F. The authorized representative shall notify the appropriate municipal officials and the depuration plant manager of the area of harvest 24 hours prior to actual harvest.
- G. The authorized representative shall mark the area designated for harvest prior to commencement of harvest operations with readily visible orange markers. In the case that more than one depuration crew is permitted to harvest in an area, the area to be harvested shall be bounded by readily visible colored markers.
- H. Harvesting in moderately contaminated areas for depuration purposes shall be undertaken only during daylight hours, except during the months of November, December, January, and February when harvesting will be permitted until 8:00 P.M. in areas approved by the Department marine patrol officer. In the event that a marine patrol officer approves an area for nighttime harvesting, the authorized representative must notify the officer at least 12 hours in advance of the planned nighttime harvest. The Department will determine the number of areas approved for nighttime harvesting.
- I. During depuration harvesting activities, harvest crew diggers shall remain in the same area, close enough for immediate supervision of all diggers at all times by the authorized representative.
- J. There shall be at least two persons in each harvesting crew at all times, including the authorized representative. Only one harvesting crew shall be permitted to harvest in moderately contaminated flats of a town on one day, unless the Department marine patrol officer gives permission for additional crews to harvest in that town at the same time.
- K. Each member of a depuration harvesting crew shall hold and possess on his person during depuration harvest activities, a current, valid commercial shellfish license.

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20.08 (20.25) Transportation and Delivery of Shellfish for Depuration

- A. All shellfish harvested from depuration areas shall be placed into an approved vehicle and the vehicle sealed immediately. Unless otherwise specified by a depuration harvesting certification, all shellfish harvested shall be transported directly to the depuration plant immediately after digging operations are completed. Transportation routes must be submitted in advance to the local marine patrol officer.
- B. The vehicles must be sealed with state seals, issued by depuration plant managers. The state seals shall be numbered sequentially and shall be used by depuration crews in strict numerical order.
- C. The vehicle used shall conform to the requirements set forth in Chapter 16.23.
- D. The authorized representative shall maintain harvest records as required under Chapter 20.07(D), the number of the seal on the vehicle, the time shellfish were placed on the vehicle. The plant manager shall also maintain records of shellfish lots, listing each lot by seal number and listing the time the lot arrived at the plant and the seal was removed from the vehicle at the plant.

20.09 (20.26) State Seals

The Department shall issue state seals for depuration harvesting purposes only to a depuration plant manager. It shall be unlawful for any person other than a depuration plant manager or an authorized representative to possess or request issuance of these state seals. Unused seals must be submitted to the Department of Marine Resources upon cancellation of a shellfish certificate or revocation of a certification to depurate.

20.10 Plant Operating Manual

- A. The depuration processor shall prepare a written Depuration Plant Operations Manual (DPOM) according to Minimum Requirements of a DPOM as described below; and update the DPOM as necessary. A copy of the DPOM shall be kept in a location readily accessible to the trained personnel responsible for the depuration activity. The minimum requirements for a DPOM shall address:**

1. Introduction including;

- (a) Status of document (to create, revise or update DPOM);**
- (b) Ownership and principal(s) involved with operation of facility;**
- (c) Address and phone number of owners and principal(s); and**
- (d) Summary of proposed use of the depuration facility including statement of objectives of the operation of the plant, species to be processed, proposed periods of facility operation, proposed sources of shellfish, including potential harvest areas, and maximum capacity of plant.**

2. Description of facility including:

- (a) Site plan drawing(s);**
- (b) Facility layout including detailed schematic of the entire depuration system;**
- (c) Schematic drawing of process;**
- (d) Product flow diagram showing product movement through facility;**
- (e) Statement that construction materials and fabrication will meet the requirements of Chapter 16, [XXXXX and XXXX?]; and**
- (f) Schematic of seawater delivery, treatment and distribution system.**

3. Design specifications of Depuration Unit including;

- (a) Depuration tank diagram including tank dimensions and construction details, influent and effluent locations, operating water level, and typical container configuration;**
- (b) Process water system describing type of system (flow through or recirculating), pretreatment and filtration systems, disinfection system, and hydraulic schematic;**
- (c) Shellfish containers construction and material meet the requirements of [16.08, 16.14, 16.16 and XXXX?]; and**
- (d) List of equipment including washing, culling, and packing equipment, material handling equipment, and cleaning and sanitizing equipment.**

4. Laboratory to be utilized for microbial analyses (in house, government agency, private commercial);

5. Depuration process monitoring including;

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- (a) Sampling protocols including frequency of sampling, number of samples, sampling locations, and methodology for process water analyzing, incoming shellstock and depurated shellstock;*
- (b) Monitoring equipment maintenance and calibration procedures and copy of activity log forms that will be used for data entry;*
- (c) Process water monitoring protocol for physical and chemical parameters; and*
- (d) Data analysis and evaluation.*
- 6. Standard Operating Procedure for:**
 - (a) Receiving and holding;*
 - (b) Washing, culling, and placement of undepurated product in process tanks;*
 - (c) Depuration unit operation;*
 - (d) Monitoring of depuration unit operation;*
 - (e) Removal of depurated product from process tanks;*
 - (f) Storage parameters and procedures;*
 - (g) Labeling/tagging procedures;*
 - (h) Plant cleaning and sanitation;*
 - (i) Data analysis; and*
 - (j) Recall procedures.*
- 7. Copies of proposed forms to be used for record keeping; a list of categories of information that will be recorded, including;**
 - (a) Shipping and receiving records;*
 - (b) Plant Operation Log, including provisions for recording the values for chemical and physical parameters;*
 - (c) Maintenance and Sanitation Log(s); and*
 - (d) Laboratory records.*

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20.11 Process Verification

- A. The dealer shall continuously perform process verification according to the following protocol:**
- 1. Following completion of a minimum of 44 hours of depuration, collect and assay at least one end-product sample from each lot of shellstock to be depurated in the depuration unit.**
 - 2. Determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each restricted harvest area used.**
 - 3. Compare daily, or as results become available, the depuration performance indices with the following Critical Limits for the Indices of Depuration Plant Performance table below:**

Limits for Verification of Depuration Plant Performance

Fecal Coliform per 100 grams

Species	Geometric Mean	90th Percentile
Soft Clams (<i>Mya arenaria</i>)	50	130
Hard Clams (<i>Mercenaria mercenaria</i>)	20	70
Oysters	20	70
Manilla Clams	20	70
Mussels	20	70

- 4. If the depuration performance indices for a specific species from a specific growing area are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance, then the process is considered verified for that species from that growing area.**

20.12 Conditional Protocol Verification

- A. If the depuration performance indicies for a specific growing area fail to meet the Critical Limits for the Indices of Depuration Plant Performance, or if a new restricted growing area is used as a source of shellfish for depuration, or if a new depuration process has generated less than 10 process batches of data, the process is considered to be unverified and the dealer shall adhere to the following conditional protocols:**
- 1. The depuration processor shall collect and assay at least one zero hour and three end-product samples from each harvest lot;**
 - 2. Environmental parameters including process water temperature, salinity, dissolved oxygen, and turbidity and/or other operational conditions may inhibit the physiological process and must be identified. The condition(s), once identified and quantified, become critical control points (CCP) for specific species in the specific plant and the hazard analysis and HACCP plan shall be revised accordingly.**
 - 3. Shellstock which are processed during this conditional protocol must meet the following release criteria before they may be released to market:**
 - (a) Geometric mean (from three samples) of soft shelled clams not to exceed 110 and no single sample to exceed 170; or**
 - (b) Geometric mean (from three samples) of other clam species, mussels, or oysters not to exceed 45 and no single sample to exceed 100.**

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4. *If the harvest lot fails to meet the release criteria, the depuration processor may choose to subject the product to additional depuration processing whereupon the shellfish can be resampled for release criteria or the disposition of the shellfish shall be as follows:*
 - (a) *The Department, in consultation with the depuration processor, may order the destruction of the shellfish; or*
 - (b) *The Department, in consultation with the depuration processor, may allow non-food use of the shellfish; or*
 - (c) *The Department, in consultation with the depuration processor, may allow the shellfish to be relayed in accordance with Chapter 21 [and XXXX?].*
5. *When depuration units with multiple tanks are used, it is necessary to determine whether the individual tanks are similar.*
 - (a) *Tanks are considered similar if the difference between physical tank dimensions and process water flow rate is less than 10%.*
 - (b) *If they are not similar, then the process verification protocols contained in Chapter 20.11 and XXXX must be employed for each tank.*
6. *All microbiological assays of end-point samples shall be analyzed by a laboratory, which has been evaluated and approved pursuant to the requirements in the NSSP Guide for the Control of Molluscan Shellfish, Revision 1999, Chapter III, using an NSSP approved method.*
7. *Sample size shall consist of a pool of at least 12 shellfish selected at random from each designated container (more than 12 individuals may be required in the case of smaller shellfish).*
8. *Samples shall be collected at locations within the depuration unit that are considered to be most compromised as regards shellfish activity, based on the sampling plan contained in the DPOM.*

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20.13 [20.23, 20.24] Records

- A. Each depuration certificate holder shall maintain the following records, in addition to those described in Chapter 15.24, 15.29, XXXX and 16.11, XXXX:
 - 1. Daily dig records as required by Chapter 20.24(I);
 - 2. Daily sales records as required by regulations promulgated under 12 M.R.S.A., §6856 and numbers of bushels received, sold and held in process tanks.
 - 3. Daily records of water flow rates in process tanks;
 - 4. Dates U.V. units cleaned and U.V. lights replaced, as well as dates process tanks, shellfish containers and mechanical washer cleaned;
 - 5. All quality assurance records required shall be maintained for at least two years.
- B. Records shall be maintained at the plant and be available for inspection by department personnel.